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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/559,694	05/01/2006	Wolfgang Kreisel	64609(70301)	3005

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EDWARDS ANGELL PALMER & DODGE LLP
P.O. BOX 55874
BOSTON, MA 02205

EXAMINER	
STONE, CHRISTOPHER R	
ART UNIT	PAPER NUMBER
1628	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/559,694	KREISEL, WOLFGANG	
	Examiner	Art Unit	
	CHRISTOPHER R. STONE	1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 October 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 11-19* is/are pending in the application.

4a) Of the above claim(s) *3,5-7,13-16 and 18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,8,9,11,12,17 and 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *09/14/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed October 6, 2009, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Status of Claims

Claims 1-9 and 11-19 are pending. Claims 3, 5-7, 13-16 and 18 are withdrawn from consideration as being drawn to nonelected subject matter. Claims 1, 2, 4, 8, 9, 11, 12, 17 and 19 are currently under examination. Vardenafil and bleeding complications of portal hypertension are the elected species of PDE 5 inhibitor and disease condition related to portal vein pressure currently under examination.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 8, 9, 11, 12, 17 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fryburg et al (WO 02/060422 A2) in view of Grofte et al (US 2002/0028764 A1).

Claims 1, 8, 9, 11, 12, 17 and 19 are drawn to a method for the therapy of a human diagnosed with portal hypertension comprising administering a PDE 5 inhibitor. Vardenafil is the elected specie of PDE 5 inhibitor currently under examination.

Fryburg et al (WO 02/060422 A2) teaches a method of treating diabetes type 2 comprising administering 0.01-20mg/kg vardenafil (dependent upon the age, weight and response of a particular patient) orally as a single dose to a human (p. 11, paragraphs 1-3). Fryburg et al does not explicitly teach the method comprising the administration to a human diagnosed with portal hypertension or the dosage specified by instant claim 19.

Grofte et al (US 2002/0028764 A1) teaches that in patients with chronic liver disease, e.g. cirrhosis of the liver, the associated secondary conditions of diabetes type 2 and portal hypertension may occur in combination (paragraphs 0059 and 0223).

Therefore, it would have been prima facie obvious to one of ordinary skill in the art to administer the treatment of Fryburg et al for the therapy of a patient diagnosed with portal hypertension and diabetes type 2, since these conditions where known to coexist in certain patient populations and the method was known to be useful in the treatment of diabetes type 2. Furthermore, with regard to the dosages specified by claim 17, it is noted that Fryburg et al teaches that vardenafil may be administered in a dosage range encompassing the instantly claimed dosage range and further teaches that the actual dosage administered to particular patient is determined by a physician, dependent upon the age, weight and response of said patient (p. 11, lines 19-26). Thus it would have been prima facie obvious to one of ordinary skill in the art to administer

vardenafil at any dosage within the range of Fryburg et al (e.g. 0.1 or 10mg/kg), based upon the age, weight and response of a particular patient, thus resulting in the practice of the instantly claimed invention with a reasonable expectation of success.

. Claims 2, 4, 8, 9, 11, 12 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fryburg et al (WO 02/060422 A2) in view of Grofte et al (US 2002/0028764 A1), as applied above, further in view of Garcia-Tsao (provided by Applicant, cited in Office Action, mailed August 5, 2008).

Fryburg et al (WO 02/060422 A2) and Grofte et al (US 2002/0028764 A1) teach the aforementioned method but do not teach the administration of vardenafil to a patient diagnosed with bleeding complications of portal hypertension, including bleeding from the esophagus varices and/or fundus varices.

Garcia-Tsao teaches that bleeding from esophageal varices is a common complication of portal hypertension (abstract). Therefore it would have been prima facie obvious to one of ordinary skill in the art at the time of the instantly claimed invention to administer vardenafil to a patient diagnosed with portal hypertension (and its common complication, bleeding from esophageal varices), and diabetes type 2, since these conditions where known to coexist in certain patient populations and vardenafil was known to be useful in the treatment of diabetes type 2, thus resulting in the practice of the instantly claimed invention with a reasonable expectation of success.

Response to Arguments

Applicant argues that Fryburg et al does not teach the instantly claimed patient population or that vardenafil treats portal hypertension. This is found unpersuasive

because, the newly applied references Grofte et al and Garcia-Tsao et al render obvious the administration of vardenafil to the instantly patient population, i.e. a patient diagnosed with portal hypertension for the reasons noted above, and the instant claims are not limited to the treatment of portal hypertension or its complications, only the therapy of a human diagnosed with the conditions.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER R. STONE whose telephone number is (571)270-3494. The examiner can normally be reached on Monday-Thursday, 7:30am-4:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brandon Fetterolf can be reached on (571) 272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CRS

/Brandon J Fetterolf/
Primary Examiner, Art Unit 1642